

# **EXHIBIT A**

# Industry Resources on the Changes to the Nutrition Facts Label

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## Food Labeling & Nutrition

[FDA Nutrition Innovation Strategy](#)

[Label Claims for Food & Dietary Supplements](#)

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[Gluten-Free Labeling of Foods](#)

[Changes to the Nutrition Facts Label](#)

[Nutrition Labeling Information for Restaurants & Retail Establishments](#)

## Food Allergies

[Nutrition Education Resources & Materials](#)

Following are resources and the most frequently asked questions we have received via our [inquiry form](#), and during presentations made to various stakeholder groups.

Additional questions will be included in guidance documents under development. This is not an exhaustive list and new questions may be added in the future to address emerging issues and topics that require clarification.

### Topics:

- [Locating Resources](#)
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- [Food Labeling Guide](#)
- [Supplement Facts Label](#)
- [Compliance](#)
- [Added Sugars](#)
- [Serving Size](#)
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- [Folic Acid and Neural Tube Defects Health Claim](#)
- [The Voluntary Nutrition Labeling of Raw Fruits, Vegetables, and Fish](#)
- [Label Claims](#)

## Locating Resources

Where can I find the final rules, guidance, and other helpful reference information related to the Nutrition Facts and Supplement Facts labels?

- **Final Rule:** [Revision of the Nutrition and Supplement Facts Labels](#) (May 2016)
- **Final Rule:** [Serving Sizes of Foods That Can Be Reasonably Consumed at One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments](#) (May 2016)
- **Final Rule:** [Food Labeling: Revision of the Nutrition and Supplement Facts Labels and Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments; Extension of Compliance Dates](#) (May 2018)

### Final Rules

[Final Rule: Revision of the Nutrition and Supplement Facts Labels](#)

See submitted comments, supporting documents, and references in [Docket No. FDA-2012-N-1210](#).

[Final Rule: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments](#)

See submitted comments, supporting documents, and references in [Docket No. FDA-2004-N-0258](#).

[Final Rule: Revision of the Nutrition and Supplement Facts Labels; Technical Amendments](#)

Provides technical amendments to the two final rules concerning Nutrition Facts and Supplement Facts labeling.

### Fact Sheets, Infographics, and Other Downloads

- [Side-by-Side of the Original and New Label](#) Infographic (Black & White PDF - 575KB) | [Español](#) (Black & White PDF - 789KB)
- [Details of Key Changes](#) 1 Page Overview (PDF - 225KB)
- [Highlights of Serving Sizes Changes](#) Infographic (PDF - 431KB) | [Español](#) (PDF - 410KB)
- [Examples of Labels in the New Format](#) (PDF - 1.7MB)
- [Preliminary Regulatory Impact Analysis for the Proposed Rules on the Nutrition Facts Label](#)

### Meetings & Workshops

- [Nutrition Facts Label Webinar](#) - June 27, 2016
- [Nutrition Facts Label Presentation](#) (PDF - 580KB)

**Content current as of:**  
01/11/2022

**Regulated Product(s)**  
Food & Beverages

**Topic(s)**  
Nutrition Label

<ul style="list-style-type: none"><li>Mints; and Technical Amendments (May 2016)</li><li><b>Final Rule:</b> <a href="#">Food Labeling: Revision of the Nutrition and Supplement Facts Labels and Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments; Extension of Compliance Dates</a> (May 2018)</li></ul>	<ul style="list-style-type: none"><li><a href="#">Preliminary Regulatory Impact Analysis to the Proposed Changes to the Nutrition Facts Label</a></li></ul> <div><b>Meetings &amp; Workshops</b><ul style="list-style-type: none"><li><a href="#">Nutrition Facts Label Webinar</a> - June 27, 2016</li><li><a href="#">Nutrition Facts Label Presentation</a> (PDF - 580KB)</li></ul></div>
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- Final Rule:** [Revision of the Nutrition and Supplement Facts Labels; Technical Amendments](#) (December 2018)
- Guidance for Industry:** [The Declaration of Allulose and Calories from Allulose on Nutrition and Supplement Facts Labels](#) (October 2020)
- Request for Information:** [Sugars that are Metabolized Differently than Traditional Sugars](#) (October 2020)
- Guidance for Industry:** [Revision of the Nutrition and Supplement Facts Labels; Small Entity Compliance Guide](#) (January 2020)
- Guidance for Industry:** [Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion, Reference Amounts Customarily Consumed, Serving Size-Related Issues, Dual-Column Labeling, and Miscellaneous Topics](#) (December 2019)
- Guidance for Industry:** [Nutrition and Supplement Facts Labels: Questions and Answers Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals](#) (Revised December 2019)
- Guidance for Industry:** [Policy Related to Cranberry Products with Added Flavorings](#) (August 2019)
- Guidance for Industry:** [Converting Units of Measure for Folate, Niacin, and Vitamins A, D, and E on the Nutrition and Supplement Facts Labels](#) (August 2019)
- Guidance for Industry:** [Declaration of Added Sugars on Honey, Maple Syrup, Other Single-Ingredient Sugars and Syrups, and Certain Cranberry Products](#) (June 2019)
- Guidance for Industry:** [The Declaration of Certain Isolated or Synthetic Non-Digestible Carbohydrates as Dietary Fiber on Nutrition and Supplement Facts Labels](#) (June 2018)
- Guidance for Industry:** [Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates Submitted as a Citizen Petition \(21 CFR 10.30\)](#) (February 2018)
- Guidance for Industry:** [Reference Amounts Customarily Consumed: List of Products for Each Product Category](#) (February 2018)
- Guidance for Industry:** [Small Entity Compliance Guide for Serving Size Final Rule](#) (February 2018)
- Guidance for Industry:** [FDA's Policy on Declaring Small Amounts of Nutrients and Dietary Ingredients on Nutrition Labels](#) (July 2016)
- Updated Daily Values**
  - updated [Daily Reference Values \(DRVs\)](#) in the final rule
  - updated [Reference Daily Intakes \(RDIs\)](#) in the final rule
- New Reference Amounts Customarily Consumed (RACCs)**
  - Starting on [page 34041](#) of the Serving Size final rule

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### Format

Is there a quick reference with all of the format requirements for the new label (e.g., font sizes)?

We received many questions about the specifications for the different label formats that were shown in the Nutrition Facts label final rule. Therefore, we are posting graphic

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## Format

### Is there a quick reference with all of the format requirements for the new label (e.g., font sizes)?

We received many questions about the specifications for the different label formats that were shown in the Nutrition Facts label final rule. Therefore, we are posting graphic illustrations depicting the changes that were made to several format displays, including the standard vertical display, standard tabular display, tabular display for small packages, and the linear display for small packages. These illustrations provide information on requirements for the use of bold font and type sizes that were established in the Nutrition Facts label final rule. We are also providing illustrations on the new Nutrition Facts label depicting other format elements that have not changed, such as line thickness, font styles, and leading specifications that were previously shown in Appendix B to Part 101, Title 21 of the CFR.

- [High-Resolution Examples of Different Labels in the New Format - Graphic Illustrations](#) (*for reference only*) (PDF - 475KB)
- [High-Resolution Examples of Different Labels in the New Format - Graphic Illustrations with Explanations of Details](#) (*for reference only*) (PDF - 408KB)

Note that, except for the hairline above the Added Sugars declaration, all hairlines between nutrients extend the full width of the label so that the hairlines almost touch the left border of all label formats (with the exception of the tabular and linear displays). We acknowledge that the dual column label formats depicted in the final rule incorrectly showed the hairlines between Saturated Fat and Trans Fat as not extending to the left edge of the label. We plan to correct this error. Additionally, a type size was inadvertently left out of the rule for the “Amount Per Serving” statement CFR 101.9(d)(1)(iii), we plan to correct that in future rulemaking.

### Will FDA be providing templates of the Nutrition Facts label for industry to use?

FDA has not provided label templates in the past and we do not plan to do so now. The use of a template would not necessarily reflect all of the factors that a company may need to consider that are unique to its product, such as the placement of information on a particular package size, the need for certain nutrition information based on label claims made elsewhere on the label, and decisions related to voluntary nutrition information that may be included or omitted. Therefore, we suggest that companies use the sample labels and graphic illustrations as visual guides when formatting their own labels..

To help industry comply with the changes described in the new regulations, we are posting graphic illustrations of several different format displays that depict the requirements and also provide examples of certain format elements that have not changed. Refer to the previous question for links. FDA is also aware that the private sector is equipped to provide labeling templates.

### Will the agency be releasing high-resolution versions of the mockups?

See [High-Resolution Examples of Different Labels in the New Format](#) (*for reference only*) (PDF - 475KB).

### Does the FDA have an example of an English/Spanish bilingual Nutrition Facts label?

For an example of an English/Spanish bilingual standard vertical label, see [Nutrition Facts/Datos de Nutrición – Bilingual Label](#) (*for reference only*) (PDF - 115KB).

### In what order should nutrients be listed on the Nutrition Facts label?

We have provided a sample label (Standard Vertical label with voluntary nutrients) on [page 33986](#) of the final rule showing the order in which the mandatory nutrients and some commonly listed voluntary nutrients are declared on food product labels. Following the “Calories” declaration located near the top of the label, the general order for listing nutrients is: macronutrients (and sodium), mandatory public health nutrients (i.e.,

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For an example of an English/Spanish bilingual standard vertical label, see [Nutrition Facts/Datos de Nutricion – Bilingual Label](#) (for reference only) (PDF - 115KB).

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The following drop-down lists summarize the order that mandatory and voluntary nutrients are generally declared on the Nutrition Facts label:

General order for listing statutorily declared nutrients and other mandatory or voluntary nutrients on the Nutrition Facts label

Order for listing voluntary vitamins and minerals on the Nutrition Facts label

In what order should nutrients be listed on the Supplement Facts label?

The order in which nutrients are listed on the Supplement Facts label is described in 21 CFR 101.36(b)(2)(i)(B) on [page 33994](#) of the final rule. Our final rule requires that choline be declared after pantothenic acid on the Supplement Facts label and that fluoride be declared at the end of the list of nutrients (i.e., after potassium). The sample label on [page 33999](#) of the final rule shows the order in which commonly listed vitamins and minerals are declared on dietary supplement labels. However, this label contains an error, as choline should be declared after pantothenic acid, rather than after potassium as it now appears. FDA plans to correct this error in a technical amendment.

The general order in which macronutrients and micronutrients in a dietary supplement product are listed on the Supplement Facts label is summarized in the following drop-down lists:

General order for listing macronutrients and vitamins on the Supplement Facts label

Order for listing minerals and micronutrients on the Supplement Facts label

FDA now permits the voluntary declaration of fluoride as provided for in §101.9(c)(5). Where should fluoride be placed on the Nutrition Facts label and how should it be formatted (i.e. indentation, bolding, etc.)?

Our current thinking is to place the declaration for “Fluoride” directly beneath the declaration of “Sodium” on the Nutrition Facts label, when fluoride is voluntarily declared pursuant to 21 CFR 101.9(c)(5). Our current thinking with regards to formatting fluoride is to list the nutrient in bold or extra bold type and not to indent the declaration; an approach consistent with the declaration of sodium, which would appear directly above the voluntary fluoride declaration. We plan to address this in future guidance.

Is it permissible to use the abbreviations identified for nutrients in §101.9(j)(13)(ii)(B) in the statement, “Not a significant source of \_\_\_\_” as required by §101.9(f)(4) when the simplified Nutrition Facts panel format is used and nutrition claims are made on the label?

The use of abbreviations for nutrients identified in 21 CFR 101.9(j)(13)(ii)(B) may be used in that statement for foods in packages that have a total surface area available to bear



pursuant to 21 CFR 101.9(c)(5). Our current thinking with regards to formatting fluoride is to list the nutrient in bold or extra bold type and not to indent the declaration, an approach consistent with the declaration of sodium, which would appear directly above the voluntary fluoride declaration. We plan to address this in future guidance.

**Is it permissible to use the abbreviations identified for nutrients in §101.9(j)(13)(ii)(B) in the statement, “Not a significant source of \_\_\_\_\_” as required by §101.9(f)(4) when the simplified Nutrition Facts panel format is used and nutrition claims are made on the label?**

The use of abbreviations for nutrients identified in 21 CFR 101.9(j)(13)(ii)(B) may be used in that statement for foods in packages that have a total surface area available to bear labeling of 40 or less square inches. The modified requirements set forth in § 101.9(j)(13)(ii)(B) do not apply to all packages that use the simplified Nutrition Facts panel, only those packages that have a total surface area available to bear labeling of 40 or less square inches.

**If there is insufficient continuous vertical space (i.e., larger than 3 inches) for the Nutrition Facts panel, can the tabular format be used?**

The regulation in § 101.9(d)(11)(iii) provides that if there is not enough vertical space (i.e., approximately 3 in.) to accommodate the required components of the Nutrition Facts label, up to and including the mandatory declaration of potassium, the nutrition label may be presented in a tabular display.

**If a package of a single-ingredient sugar or syrup meets the criteria for the use of the linear display for small or intermediate-sized packages, what should the label look like?**

The linear display for small or intermediate-sized packages may be used if a package or container of a single-ingredient sugar or syrup has a total surface area to bear labeling of 40 or less square inches and the label will not accommodate a tabular display. Although the declaration of the gram amount of Added Sugars is not required on the labels of single-ingredient sugars and syrups, these foods contribute added sugars to the diet when consumed, and the percent Daily Value (%DV) for Added Sugars (preceded by a blank space) must be declared on the label, regardless of the format used. If the linear display for small or intermediate-sized packages is used on a single-ingredient sugar or syrup product, we encourage the placement of the “+” symbol next to the percent %DV declaration for Added Sugars. The “+” should direct consumers to a statement that is truthful and not misleading within a footnote in the Nutrition Facts label box that includes a description of the gram amount of sugar added to the diet by one serving of the product and its contribution to the %DV for Added Sugars in the diet. The following is an example of what the linear display may look like on a small or intermediate-sized container of honey:

**Nutrition Facts** Servings: 16, **Serv. size: 1 Tbsp (21g),**  
Amount per serving: **Calories 60**, **Total Fat** 0g (0% DV), **Sat. Fat** 0g (0% DV),  
**Trans Fat** 0g, **Cholest.** 0mg (0% DV), **Sodium** 0mg (0% DV), **Total Carb.** 17g (6% DV),  
**Fiber** 0g (0% DV), **Total Sugars** 17g, ( , 34% DV), **Protein** 0g,  
**Vit. D** (0% DV), **Calcium** (0% DV), **Iron** (0% DV), **Potas.** (0% DV).  
† One serving adds 17g of sugar to your diet and represents 34% of the Daily Value for Added Sugars.

Manufacturers may also choose to use the simplified format if the product is not a significant source of certain nutrients. In the example above, the declarations of Sat. Fat, Trans Fat, Cholest., Fiber, Vit. D, Calcium, Iron, and Potas. could be removed, and the statement “Not a significant source of sat. fat, trans fat, cholest., fiber, vit. D, calcium, iron, and potas.” could be placed above the footnote.

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## Food Labeling Guide

### Is FDA planning to update the labeling guide posted on your website?

We are working on updating our current [Food Labeling Guide](#) to incorporate the changes to the Nutrition and Supplement Facts labels, but this will take some time. Parts of the labeling guide are up to date including the net quantity statements, ingredient lists, and claims information. While the Nutrition Labeling section of Food Labeling Guide is being updated, the nutrition labeling changes are addressed in our final rules that updated the

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## Supplement Facts Label

### Did the format change for the Supplement Facts Label? How big should the calorie declaration be for the Supplement Facts label?

The format of the Supplement Facts label did not change substantially. Similar to the Nutrition Facts label, we no longer require vitamin A, vitamin C, or calories from fat to be declared as (b)(2) dietary ingredients, and instead we require vitamin D, potassium, and added sugars to be declared. In addition, we have replaced “sugars” with “total sugars” in the list of (b)(2) dietary ingredients, and we have made several changes in the order in which vitamins and minerals are listed (for example, when declared, choline must follow pantothenic acid on the label and fluoride must be at the end of the list of nutrients, below potassium when it is declared), as described on page 33933 of the final rule (§ 101.36(b)(2)(i)(B)). Furthermore, we have updated the Daily Values based on recent science, and we updated the units of measures. Also, we are requiring a footnote for labels of certain products represented or purported to be for use by children 1 through 3 years of age as shown in § 101.36(e)(11)(ii) (Please see Section P beginning on [page 33932](#) of the [final rule](#)).

The calorie declaration on the Supplement Facts label does not need to be as prominent as on the Nutrition Facts label because many dietary supplements do not contribute a significant amount of calories to the diet. Therefore, as we state on [page 33939](#) of the final rule, we are not requiring that information about calories be displayed in a larger type size or be highlighted in bold type or extra bold on any Supplement Facts label. In a future technical amendment, we intend to correct the error in the codified section of the final rule (§ 101.36(e)), which states that a font size at least two points greater [than 8 point] shall be used for “Calories” and the heading “Calories” and the actual number of calories per serving shall be highlighted in bold or extra bold type.

- [High-Resolution Examples of Different Supplement Facts Labels in the New Format](#) (*for reference only*) (PDF - 579KB)

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## Compliance

### What are the compliance dates for the new requirements?

On May 3, 2018, the FDA issued a final rule to extend the compliance dates for the Nutrition Facts and Supplement Facts label and Serving Size final rules from July 26, 2018, to Jan. 1, 2020, for manufacturers with \$10 million or more in annual food sales. Manufacturers with less than \$10 million in annual food sales had an additional year to comply – until Jan. 1, 2021. Manufacturers of most single-ingredient sugars such as honey and maple syrup and certain cranberry products have until July 1, 2021, to make the changes. Manufacturers of certain flavored dried cranberries had until July 1, 2020, to make the changes. These compliance dates are still in place.

However, the FDA has heard from some manufacturers that more time may be needed to meet all of the requirements, especially during the COVID-19 pandemic. Therefore, FDA is not currently focusing on enforcement actions regarding these new requirements.

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However, the FDA has heard from some manufacturers that more time may be needed to meet all of the requirements, especially during the COVID-19 pandemic. Therefore, FDA is not currently focusing on enforcement actions regarding these new requirements.

FDA recognizes the public health importance of ensuring that consumers have access to the new Nutrition Facts label, and this new label appears on the majority of food packages. FDA continues to work cooperatively with manufacturers to meet the new Nutrition Facts label requirements.

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## Added Sugars

### How does the FDA define “added sugars”?

The definition of added sugars includes sugars that are either added during the processing of foods, or are packaged as such, and include sugars (free, mono- and disaccharides), sugars from syrups and honey, and sugars from concentrated fruit or vegetable juices that are in excess of what would be expected from the same volume of 100 percent fruit or vegetable juice of the same type. The definition excludes fruit or vegetable juice concentrated from 100 percent fruit juice that is sold to consumers (e.g. frozen 100 percent fruit juice concentrate) as well as some sugars found in fruit and vegetable juices, jellies, jams, preserves, and fruit spreads. However, although they are still “added sugars,” single-ingredient sugars such as pure honey, maple syrup, and a bag of sugar, have different labeling requirements from other added sugars.

### How will single-ingredient sugars like packages and containers of pure honey, maple syrup, and other pure sugars and syrups be labeled?

These products have different labeling requirements. They are not required to include the number of grams of Added Sugars in a serving of the product but must still include a declaration of the percent Daily Value for Added Sugars. Manufacturers are encouraged to use the “+” symbol immediately following the Added Sugars percent Daily Value on single-ingredient sugars and syrups, which would lead to a truthful and not misleading statement in a footnote explaining the amount of added sugars that one serving of the product contributes to the diet as well as the contribution of a serving of the product toward the percent Daily Value for added sugars.

An example of such labeling using the standard vertical format is available in FDA’s fact sheet for [The Nutrition Facts Label: Declaration of Added Sugars for Single-Ingredient Sugars and Certain Cranberry Products](#). For an example of a linear label for small or intermediate-sized packages, please see the question under Format on [use of the linear label for small or intermediate-sized packages](#) on a package or container of a single-ingredient sugar or syrup.

### How will sugars and syrups that contain two or more ingredients be labeled?

All packages and containers of sugars and syrups with two or more ingredients must have both the gram declaration and percent Daily Value for Added Sugars on their Nutrition Facts labels. For example, products such as brown sugar consisting of a combination of cane sugar and cane molasses, powdered sugar containing corn starch, or a pure syrup with added flavoring must declare the gram and percent Daily Value for Added Sugars. All of the sugars in multiple-ingredient sugar and syrup products must be declared as Added Sugars.

Only manufacturers of single ingredient sugars and syrups may omit “Includes Xg Added Sugars” from the Added Sugars line on the Nutrition Facts label. This exemption arose from concerns about consumers potentially being misled to believe that the declaration of “Added Sugars” on single-ingredient sugars and syrups means exogenous (originating from outside the product) sweeteners have been added, which could mean the products



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Only manufacturers of single ingredient sugars and syrups may omit “Includes Xg Added Sugars” from the Added Sugars line on the Nutrition Facts label. This exemption arose from concerns about consumers potentially being misled to believe that the declaration of “Added Sugars” on single-ingredient sugars and syrups means exogenous (originating from outside the product) sweeteners have been added, which could mean the products are adulterated. The exemption does not apply to products that contain multiple sugars, syrups or other ingredients, including flavorings.

#### **Do cranberry products have to include an Added Sugars declaration?**

The number of grams of Added Sugars in a serving of the product, as well as the percent Daily Value for Added Sugars, must still be labeled for cranberry products. FDA intends to exercise enforcement discretion for certain cranberry products to allow for the use of a symbol leading to a statement that is truthful and not misleading placed outside the Nutrition Facts label. Manufacturers could explain, through the use of the statement, that the sugars added to these dried cranberries or cranberry beverage products are meant to increase the palatability of the naturally tart fruit and that the amount of total sugars per serving is at a level that does not exceed the amount of total sugars in a comparable product with no added sugars. See FDA’s fact sheet for [The Nutrition Facts Label: Declaration of Added Sugars for Single-Ingredient Sugars and Certain Cranberry Products](#).

#### **Do sugars found in concentrated fruit or vegetable purees and pastes need to be declared as added sugars on the label?**

We have received a number of inquiries related to this topic since publication of the final rule. Additional information is available in our [Draft Guidance for Industry: Questions and Answers on the Nutrition and Supplement Facts Labels Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals](#).

We intend to respond to questions we received on the draft guidance about concentrated fruit or vegetable purees and pastes when we issue the final guidance.

#### **FDA has standardized Brix data for a variety of juices (§ 101.30(h)) but this table does not include all of the common fruit/vegetable juices used to formulate products today (e.g., coconut water, acai juice). Does FDA plan to update the Brix table in § 101.30(h)?**

We are not planning to update the Brix table in 21 CFR 101.30(h) at this time. The mechanism for requesting the addition to the table of a Brix level for a single strength juice is the submission of a Citizen Petition (CP) (21 CFR 10.30). The addition to the table in § 101.30(h)(1) of a Brix level for a new single strength juice would require FDA to amend the regulation to update the table.

We intend to respond to questions relation to the calculation of added sugars in juices in the final guidance on Questions and Answers on the Nutrition and Supplement Facts Labels Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals.

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## **Serving Size**

**Some products have a RACC of 30 grams, which needs to be converted to a household measure for the serving size. A RACC of 30 grams is approximately equal to a household measure of 1 ounce, but 1 ounce technically weighs 28.35 grams. If the household serving size is 1 ounce, should the gram weight equivalent of the label serving size be 30 grams or rounded to 28 grams?**

For nutrition labeling purposes, if the household serving size is 1 ounce, manufacturers should use 28 grams as the rounded metric weight equivalent, as explained in 21 CFR 101.9(b)(5)(viii).

**How do I know to which RACC product category my product belongs?**

Some products have a RACC of 30 grams, which needs to be converted to a household measure for the serving size. A RACC of 30 grams is approximately equal to a household measure of 1 ounce, but 1 ounce technically weighs 28.35 grams. If the household serving size is 1 ounce, should the gram weight equivalent of the label serving size be 30 grams or rounded to 28 grams?

For nutrition labeling purposes, if the household serving size is 1 ounce, manufacturers should use 28 grams as the rounded metric weight equivalent, as explained in 21 CFR 101.9(b)(5)(viii).

#### How do I know to which RACC product category my product belongs?

In February 2018, we issued [Final Guidance for Industry: Reference Amounts Customarily Consumed: List of Products for Each Product Category](#) to help industry identify the product category to which specific products belong by providing a non-exhaustive list of product examples that belong in each of the product categories included in the RACC tables established in 21 CFR 101.12(b).

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## Dual-Column Labeling/Single-Serving Containers

**Are product labels that voluntarily provide an additional column of nutrition information per unit when the serving size of a product in discrete units in a multi-serving container is more than 1 unit exempt from dual-column labeling requirements, when dual-column labeling would otherwise be required?**

There is no specific exemption from dual-column labeling requirements for product labels that voluntarily provide an additional column of nutrition information per unit.

Under § 101.9(b)(10)(ii), another column of nutrition information may be used voluntarily to declare the nutrient and food component information per one unit if the serving size of a product in discrete units is more than one unit. This provision does not exempt the product from other applicable labeling requirements (e.g., dual-column labeling requirements); therefore, any nutrition information provided under § 101.9(b)(10)(ii) would be provided in addition to other required nutrition information. For products in discrete units, applicable requirements are in § 101.9(b)(2)(i). Under § 101.9(b)(2)(i)(D), if a unit weighs at least 200 percent and up to and including 300 percent of the applicable reference amount, the Nutrition Facts label shall bear two columns of information:

- The first column shall provide nutrition information per serving size, which shall be the amount that approximates the reference amount (e.g., 1/2 piece).
- The second column shall provide the quantitative amounts and percent Daily Values per individual unit.

Note that the exemptions in paragraphs (A), (B), and (C) of § 101.9(b)(12)(i) apply to labels subject to the requirements of § 101.9(b)(2)(i)(D).

**Is a manufacturer permitted to voluntarily provide an additional column of nutrition information on the serving size as determined by the RACC for products that meet the criteria for the single-serving container definition as described in § 101.9(b)(6)? The product label described in this scenario would have two columns of nutrition information: (1) serving size as determined by the RACC and (2) serving size based on the entire contents of the container.**

For products that meet the definition of a single-serving container, the serving size is the container, not the amount most closely approximating the RACC. Including nutrition information based on the serving size (in this scenario, the full container) is not voluntary. However, under § 101.9(b)(6), in addition to providing a column within the Nutrition Facts label that lists the quantitative amounts and percent Daily Values per serving, for a product that is packaged and sold individually that contains more than 150 percent and less than 200 percent of the applicable reference amount, the Nutrition Facts label may voluntarily provide, to the left of the column that provides nutrition information per container (i.e., per serving), an additional column that lists the quantitative amounts and percent Daily Values per common household measure that most closely approximates the reference amount.

For products that meet the definition of a single-serving container, the serving size is the common household measure most closely approximating the RACC. Including nutrition information based on the serving size (in this scenario, the full container) is not voluntary. However, under § 101.9(b)(6), in addition to providing a column within the Nutrition Facts label that lists the quantitative amounts and percent Daily Values per serving, for a product that is packaged and sold individually that contains more than 150 percent and less than 200 percent of the applicable reference amount, the Nutrition Facts label may voluntarily provide, to the left of the column that provides nutrition information per container (i.e., per serving), an additional column that lists the quantitative amounts and percent Daily Values per common household measure that most closely approximates the reference amount.

**For products that meet the criteria for the single-serving container definition and the label voluntarily discloses nutrition information on a “per unit” basis in addition to a “per serving” basis and bears a nutrient content claim, should the nutrient content claim be based on the serving (i.e., the entire contents of the container) or the unit?**

As explained in the [Serving Size Final Rule](#), nutrient content claims typically must be based on the RACC, but in some cases they must be based on both the RACC and a per-label serving size (81 FR 34000, 34010, May 27, 2016). Nothing in the Serving Size Final Rule changed the preexisting requirements for nutrient content claims for those who choose to voluntarily provide a second column of nutrition information. However, under the Serving Size Final Rule, when a nutrient content claim is made on the label of a product that uses a dual column as required in § 101.9(b)(2)(i)(D) or (b)(12)(i), the claim must be followed by a statement that sets forth the basis on which the claim is made, except that the statement is not required for products when the nutrient that is the subject of the claim meets the criteria for the claim based on both the RACC and the entire container or unit amount. All information included on a product label must be truthful and not misleading.

**If a manufacturer chooses to voluntarily include an additional column of RACC-based nutrition information for a product that is packaged and sold individually, that contains more than 150% and less than 200% of the applicable RACC, how should the serving size and servings per container be based?**

Voluntarily choosing to provide an additional column of information does not change the serving size of the product. Under § 101.9(b)(6), a product that is packaged and sold individually that contains less than 200 percent of the applicable reference amount must be considered to be a single-serving container, and the entire content of the product must be labeled as one serving.

**For variety packs where there is more than one of each product, what is the appropriate presentation for the servings per container to indicate the number of servings of each product?**

FDA did not substantively amend § 101.9(d)(13)(i) and (ii) except to maintain consistency of the aggregate display with the other label formats illustrated in 101.9(d). Under § 101.9(d)(13):

- Nutrition labels on the outer label of packages of products that contain two or more separately packaged foods that are intended to be eaten individually (e.g., variety packs of cereals or snack foods) or of packages that are used interchangeably for the same type of food (e.g., round ice cream containers) may use an aggregate display, and
- Aggregate displays shall comply with the format requirements of § 101.9(d) to the maximum extent possible, except that the identity of each food shall be specified immediately to the right of the “Nutrition Facts” heading, and both the quantitative amount by weight (i.e., g/mg/mcg amounts) and the percent Daily Value for each nutrient shall be listed in separate columns under the name of each food.

For an example of the correct format for the aggregate display, see [page 33987](#) of the final rule entitled “[Food Labeling: Revision of the Nutrition and Supplement Facts Label](#)” (81 FR 33742 at 33987).

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Aggregate displays shall comply with the format requirements of § 101.9(a) to the maximum extent possible, except that the identity of each food shall be specified immediately to the right of the "Nutrition Facts" heading, and both the quantitative amount by weight (i.e., g/mg/mcg amounts) and the percent Daily Value for each nutrient shall be listed in separate columns under the name of each food.

For an example of the correct format for the aggregate display, see [page 33987](#) of the final rule entitled "[Food Labeling: Revision of the Nutrition and Supplement Facts Label](#)" (81 FR 33742 at 33987).

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## Folic Acid and Neural Tube Defects Health Claim

**Due to the new requirements in the updated Nutrition Facts label (NFL), some conflicts with existing requirements in certain health claims have been noted. For example, "folate" and "folic acid" are currently permitted to be used interchangeably in the health claim for "Folic Acid and Neural Tube Defects" (21 CFR 101.79). However, under the updated NFL regulations (21 CFR 101.9), these terms are no longer considered interchangeable and only folic acid is declared on the NFL. How should manufacturers use these health claims when the requirements for the claim are different from or inconsistent with the requirements of the updated NFL?**

We are aware that there are existing requirements for individual health claims that are now inconsistent with the information in the updated NFL regulations. FDA is moving forward to evaluate and update all claims as necessary within the context of agency priorities and resources. We advise manufacturers that if their product(s) had previously been eligible for the use of a health claim based on the existing requirements of a specific health claim, that they may continue to use the health claim and should continue to follow the requirements for each individual claim in the existing regulations, even in light of inconsistencies with the updated NFL information. We similarly advise that new products that are introduced to the market and intend to use a health claim should follow the requirements for each individual claim in the existing regulations even if inconsistent with the updated NFL.

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## The Voluntary Nutrition Labeling of Raw Fruits, Vegetables, and Fish

**Some conflicts exist between the labeling requirements in the guidelines for the voluntary nutrition labeling of raw fruits, vegetables, and fish and the updated Nutrition Facts Label and Serving Size regulations. For example, the Daily Values for some nutrients in the updated 21 CFR 101.9 no longer correspond to the % Daily Value listed in Appendices C and D to 21 CFR part 101. How should industry (e.g., retailers, growers, producers, and shippers) prepare the nutrition labeling materials at the point-of-purchase (e.g., posters) and the Nutrition Facts labels for raw fruits, vegetables, and fish, particularly for the products that are identified among the 20 most frequently consumed?**

We are aware that the existing labeling requirements in the guidelines for voluntary labeling of raw fruits, vegetables, and fish are now inconsistent with the information in the updated Nutrition Facts Label and Serving Size regulations. FDA is moving forward to evaluate and update the voluntary labeling guidelines as necessary within the context of agency priorities and resources. The nutrition labeling of raw fruits, vegetables, and fish remains voluntary unless a claim or a statement about nutrient is made. We advise industry to continue following all subsections of 21 CFR 101.45 and Appendices C and D to 21 CFR part 101, until sections 21 CFR 101.42 to 21 CFR 101.45 have been amended to reflect the changes in the Nutrition Facts Label and Serving Size regulations. If the product is named as one of the 20 most frequently consumed raw commodities (e.g., apple) and included in 21 CFR 101.44 and Appendices C and D to 21 CFR part 101, the nutrition labeling values of these Appendices must still be used until updated.

**How can industry (e.g., retailers, growers, producers, and shippers) present nutrition information if their product is labeled as a specific variety cultivar**



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evaluate and update the voluntary labeling guidelines as necessary within the context of agency priorities and resources. The updated labeling of raw fruits, vegetables, and fish remains voluntary unless a claim or a statement about nutrient is made. We advise industry to continue following all subsections of 21 CFR 101.45 and Appendices C and D to 21 CFR part 101, until sections 21 CFR 101.42 to 21 CFR 101.45 have been amended to reflect the changes in the Nutrition Facts Label and Serving Size regulations. If the product is named as one of the 20 most frequently consumed raw commodities (e.g., apple) and included in 21 CFR 101.44 and Appendices C and D to 21 CFR part 101, the nutrition labeling values of these Appendices must still be used until updated.

**How can industry (e.g., retailers, growers, producers, and shippers) present nutrition information if their product is labeled as a specific variety, cultivar, or species (e.g., Granny Smith Apple) different from products listed on the 20 most frequently consumed raw fruits, vegetables, and fish (e.g., apple)?**

If the product is identified as one of the 20 most frequently consumed raw fruits, vegetables, or fish (e.g., apple), but the product label shows a name and description that are specific to a variety, cultivar, or species that is not specifically identified among the 20 most frequently consumed (e.g., Granny Smith apple), industry may create the nutrition labeling materials and the Nutrition Facts label using the nutrition labeling values in Appendices C and D to 21 CFR part 101 that may not reflect the updated Nutrition Facts Label and Serving Size regulations (21 CFR 101.9 and 101.12). However, they may also use industry-determined nutrition labeling values as provided for in 21 CFR 101.45(c).

When industry uses its own nutrient values (which does not preclude some of the nutrient values in Appendices C and D to 21 CFR part 101, if appropriate), the label must clearly show the name of the product that is not specifically identified among the 20 most frequently consumed, such as Granny Smith apple. The determination of nutrition labeling values is up to industry.

When the product is named as a specific variety, cultivar, or species that is not specifically identified among the 20 most frequently consumed, and industry uses its own nutrient values including some of the nutrient values in Appendices C and D to 21 CFR part 101 if applicable, it would be appropriate to apply the updated Nutrition Facts Label and Serving Size regulations in 21 CFR 101.9 and 21 CFR 101.12.

**How can industry (e.g., retailers, growers, producers, and shippers) present nutrition information if their product is not one of the 20 most frequently consumed raw commodities listed in 21 CFR 101.44?**

When the product is not one of the 20 most frequently consumed raw commodities (e.g., mango), it would be appropriate to apply the updated Nutrition Facts Label and Serving Size regulations in 21 CFR 101.9 and 21 CFR 101.12. FDA does not provide nutrition labeling values for products that are not one of the 20 most frequently consumed raw commodities. Therefore, the determination of nutrition labeling values is up to industry.

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## Label Claims

**There are separate methods for determining the number of grams of protein in a serving for declaration on the Nutrition Facts label and for determining the percent Daily Value of protein for the Nutrition Facts label (21 CFR 101.9(c)(7)). Which method should be used when calculating protein values for use in protein nutrient content claims?**

The regulation for nutrient content claims in 21 CFR 101.13(o) states that, except as provided in 21 CFR 101.10, compliance with requirements for nutrient content claims in this section and in the regulation in subpart D of this part, will be determined using the analytical methodology prescribed for determining compliance with nutrition labeling in 21 CFR 101.9.

By design, 21 CFR 101.9(c)(7) specifically provides for two different methods for determining protein values. The regulation states, in 21 CFR 101.9(c)(7), that protein content may be calculated on the basis of the factor 6.25 times the nitrogen content of the food as determined by the appropriate method of analysis as given in the “Official Methods of Analysis of the AOAC International,” except that when official AOAC procedures described in 21 CFR 101.9(c)(7) require a specific factor other than 6.25, that specific



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The regulation for nutrient content claims in 21 CFR 101.13(o) states that, except as provided in 21 CFR 101.10, compliance with requirements for nutrient content claims in this section and in the regulation in subpart D of this part, will be determined using the analytical methodology prescribed for determining compliance with nutrition labeling in 21 CFR 101.9.

By design, 21 CFR 101.9(c)(7) specifically provides for two different methods for determining protein values. The regulation states, in 21 CFR 101.9(c)(7), that protein content may be calculated on the basis of the factor 6.25 times the nitrogen content of the food as determined by the appropriate method of analysis as given in the “Official Methods of Analysis of the AOAC International,” except that when official AOAC procedures described in 21 CFR 101.9(c)(7) require a specific factor other than 6.25, that specific factor shall be used. Additionally, 21 CFR 101.9(c)(7)(ii) provides the method for determining protein content using the protein digestibility-corrected amino acid score for use in calculating the percent Daily Value.

Determination of compliance for protein nutrient content claims will be based on the use of the methods provided in 21 CFR 101.9(c)(7), including either of the methods mentioned above.

**Sugar content claims described in 21 CFR 101.60(c), such as “sugar free” and “no sugar,” are required to be accompanied by a statement that the food is “not a reduced calorie food,” “not a low calorie food,” or “not for weight control” if the food is not labeled as “low calorie” or “reduced calorie.” Does 21 CFR 101.60(c) require a statement of the amount of total sugars (“o g total sugars”), as described in 21 CFR 101.13(i)(3), to be accompanied by those additional statements?**

Title 21 CFR 101.60(c) discusses certain sugar content claims and the specific conditions for their use, including the conditions for requiring the accompanying statements “not a reduced calorie food,” “not a low calorie food,” or “not for weight control.” Statements about the amount of the nutrient in a food, which would include “o g total sugars,” are provided for in 21 CFR 101.13(i), which discusses the specific conditions for their use. Although amount statements are nutrient content claims and would, therefore, have to follow the general requirements for nutrient content claims, amount statements need not follow the requirements provided for specific, individual nutrient content claims as described in Subpart D of 21 CFR 101 (21 CFR 101.54 – 101.67). As such, 21 CFR 101.60(c) does not require “o g total sugars” amount statements to be accompanied by the additional statements.

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